

REMARKS

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

Group I, claims 1-16 and 52, drawn to a genetically modified mammal

Group II, claims 17-32, drawn to genetically modified cells

Group III, claim 33, drawn to a hybridoma

Group IV, claims 34-49 and 53, drawn to chimeric detectably labeled immunoglobulin molecules

Group V, claims 50-51, drawn to methods of making polyclonal or monoclonal antibodies

Responsive to the Requirement for Restriction, Applicants elect to prosecute the invention of Group I, claims 1-16 and 52, drawn to a genetically modified mammal, with traverse.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define genetically modified mammals and genetically modified cells, with properties so distinct as to warrant separate Examination and Search. Claims 1-16, and 52 are drawn to a genetically modified mammal capable of expressing at least one chimeric immunoglobulin gene comprising at least one detectable protein or peptide fused with a gene expressing an immunoglobulin component, selected from the group consisting of the kappa immunoglobulin light chain, the lambda immunoglobulin light chain, an immunoglobulin heavy chain, and any combination thereof, wherein antibodies secreted by the immune cells of said genetically modified mammal comprise said at least one detectable protein or peptide, and are fundamentally related to Claims 17-32 of Group II, drawn to genetically modified cells.

Applicants respectfully assert that the search for any of the characteristics of the genetically modified mammals separately classified by the Examiner as the invention of Group I would require an additional search of the identical classes wherein the invention of Group II are classified, thus resulting in a duplicate search for the same material.

Applicants respectfully draw the Examiner's attention to the fact that the genetically modified immune cells of Group II are produced by, and isolated from, the genetically modified mammals of Group I (for support, please see the specification on page 10, lines 9-16). Accordingly, the genetically modified immune cells of Group II have the identical characteristics as the immune cells derived from the genetically modified mammal of Group I and secrete the chimeric antibody as described in claim 1 (for further support, please see the specification on page 2, lines 19-22, continuing on to page 3, lines 1-11, and page 4, lines 12-22, continuing on to page 5, lines 1-4). Thus, a search on the claims elected by way of the response to the restriction requirement would require a search on the characteristics of the immune cells found in the genetically modified mammal, since the claims of Group I read on chimeric antibodies secreted by the immune cells of the genetically modified mammal. Applicants assert that such a search would result in identification of identical subject matter covered in claims 17 through 32, which read on immune cells expressing the same chimeric immunoglobulin gene.

Thus, Applicants submit that the Search and Examination of the entire Application, or, at least, of Group I with Group II can be made without serious burden, and therefore the Examiner must examine all of the claims, or in the alternative, at least those of Groups I and II, of the Application on the merits.


The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the Claims of the

present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include the Claims drawn to Group I and Group II is in order.

No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, withdrawal of the Requirement for Restriction is requested, and an early action on the merits of the Claims is courteously solicited.

Respectfully submitted,

A handwritten signature in cursive script, reading "Veronica Mallon".

Veronica Mallon, Ph.D.
Agent for Applicant(s)
Registration No. 52,491

KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 487-5800

Date: October 8, 2003